

**REMARKS**

Claims 15-22 and 24-30 are pending in the application. Of the above claims 21, 22 and 24-28 were withdrawn from consideration as non-elected inventions in response to a restriction requirement mailed on June 7, 2002. Applicants retain the right to present claims 21, 22 and 24-28 in a divisional application. Claims 15-20, 29 and 30 stand rejected. Claim 18 is objected to. Claims 15, 16, and 18 are amended herein. Support for these amendments can be found at page 5, line 9-14 and page 5, line 27 through page 6 line 8 as well as throughout the Examples of the specification. Claims 19-20 are cancelled. New claims 31 and 32 are added. Support for new claims 31 and 32 can be found at page 5, line 27 through page 6, line 5. No new matter has been added.

**Claims Objections**

The Examiner alleges that should claim 17 be found allowable, claim 18 will be objected to under 37 C.F.R. 1.75. The Examiner alleges that the phrase "has" in claim 18 is an open term just as the transitional "comprising" in claim 17. She suggests replacing "has" with the phrase "consists of" in claim 18. Applicants have herein amended claim 18 to recite "consists of" rather than the word "has."

**35 U.S.C.  112, second paragraph**

Claims 15-20 and 29-30 stand rejected under 35 U.S.C.   112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, with respect to claims 15-20, the Examiner alleges that it is unclear if "isolation/purification of the polypeptide is required in step a of claims 15 and 16 since it is not a specific step." Applicants have herein amended claims 15 and 16 to include at least partial purification of a polypeptide as an explicit step in the claimed process. Support for this amendment can be found, for example, at page 5, lines 9-15 and page 5, line 27 through page 6, line 8 of the specification. Applicants have cancelled claims 19-20 herein, thus, rendering rejection of these claims moot. Applicants

respectfully submit that as claims 17-18 and 29-30 depended from amended claims 15 and 16, these claims are now in condition for allowance.

Claims 19-20 also stand rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner alleges that the phrase “native to” in claim 19 is unclear as to the claim’s metes and bounds. Applicants have cancelled claims 19-20 herein, thus, rendering rejection of these claims moot.

In addition, Applicants have added new claims 31 and 32 which depend from claims 15 and 16, respectively. Support for new claims 31 and 32 can be found at page 5, line 27 through page 6, line 5 of the specification.

**35 U.S.C. §112, first paragraph**

Claims 19-20 also stand rejected under 35 U.S.C. § 112, first paragraph. Applicants have cancelled claims 19-20 herein, thus, rendering rejection of these claims moot.

**35 U.S.C. § 102(b)**

Claims, 15-20 and 29-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Jensen, *et al.* (CA 2,108,113) as evidenced by Li, *et al.* (*J. Bacteriol.* (2002) 182(14):4087-4095). Specifically, the Examiner alleged that Jensen, *et al.* teach an 11.6 kb clavulanic biosynthetic gene cluster from *S. clavuligerus* that contains an ORF3, wherein ORF3 is identical to SEQ ID NO:1 of the instant specification. The Examiner further alleges that within Example 4 Jensen, *et al.* inherently disclose production of  $\beta$ -lactam synthetase. Finally, the Examiner alleges that “because the pathway used by the gene-cluster-encoded enzyme encompasses a step of converting N<sup>2</sup> (2-carboxyethyl)-(S)-arginine to  $\beta$ -lactam deoxyguanidinoproclavaminac acid (See Li, *et al.*, Fig. 1, particularly the step marked Orf3), the inherently produced SEQ ID NO:2 polypeptide is inherently contacted with N<sup>2</sup> (2-carboxyethyl)-(S)-arginine to inherently produce  $\beta$ -lactam deoxyguanidinoproclavaminac acid.”

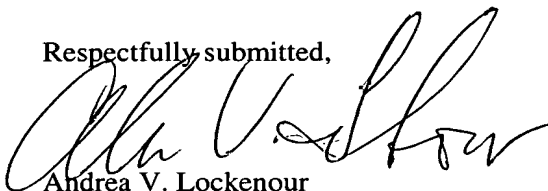
The Examiner concedes that Jensen, *et al.* do not recognize the function of their disclosed ORF3 and that the conversion of N<sup>2</sup> (2-carboxyethyl)-(S)-arginine to  $\beta$ -lactam

deoxyguanidinoproclavaminac acid is first disclosed in the instant application. The Examiner suggests that the inclusion of an "explicit purification step for the of  $\beta$ -lactam synthetase from the host cell" in the instant claims would overcome the rejection of claims 15-20 based on Jensen, *et al.*

Solely for purposes of advancing the prosecution of this case, and not acquiescing in this rejection, the Applicants have amended claims 15 and 16 as the Examiner suggests to include an explicit purification step. Support for this amendment can be found at page 5, lines 9-15 and page 5, line 27 through page 6, line 8 of the specification. Applicants respectfully submit that these claims are now in condition for allowance. Applicants have cancelled claims 19-20 herein, thus, rendering rejection of these claims moot. Applicants respectfully submit that as claims 17-18 and 29-30 depended from amended claims 15 and 16, these claims are now in condition for allowance.

Applicants respectfully submit that the aforementioned amendments and remarks are fully responsive to the Office Action and request reconsideration of the rejections stated therein. The Examiner is invited to contact Applicants' undersigned attorney at the telephone number provided below if such might facilitate allowance of the pending claims.

Respectfully submitted,



Andrea V. Lockenour  
Attorney for Applicants  
Registration No. 51,962

GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
Phone (610) 270-7568  
Facsimile (610)270-5090  
n:\avl\patapps\p32085\roa after rce.doc